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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/063,125

03/22/2002

Lex P. Jansen

10527-606001

5949

26161 7590 05/26/2009

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EXAMINER

SEVERSON, RYAN J

ART UNIT

PAPER NUMBER

3731

NOTIFICATION DATE

DELIVERY MODE

05/26/2009

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**BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES**

Application Number: 10/063,125
Filing Date: March 22, 2002
Appellant(s): JANSEN ET AL.

Geoffrey P. Shipsides
For Appellant

EXAMINER'S ANSWER

This is in response to the appeal brief filed 03 March 2009 appealing from the Office action mailed 16 October 2008.

(1) Real Party in Interest

A statement identifying by name the real party in interest is contained in the brief.

(2) Related Appeals and Interferences

The examiner is not aware of any related appeals, interferences, or judicial proceedings which will directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal.

(3) Status of Claims

The statement of the status of claims contained in the brief is correct.

(4) Status of Amendments After Final

The appellant's statement of the status of amendments after final rejection contained in the brief is correct.

(5) Summary of Claimed Subject Matter

The summary of claimed subject matter contained in the brief is correct.

(6) Grounds of Rejection to be Reviewed on Appeal

The appellant's statement of the grounds of rejection to be reviewed on appeal is substantially correct. The changes are as follows:

NEW GROUNDS OF REJECTION

Claims 1, 3, 6-8, 26-28 and 32-38 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

(7) Claims Appendix

The copy of the appealed claims contained in the Appendix to the brief is correct.

(8) Evidence Relied Upon

4,800,882	Gianturco	01-1989
5,630,840	Mayer	05-1997
5,632,840	Campbell	05-1997

(9) Grounds of Rejection

The following ground(s) of rejection are applicable to the appealed claims:

Claims 1, 3, 6-8, 26-28 and 32-38 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claims 1 and 32, lines 4 and 5 (of each claim) recite the body of the stent *consisting essentially of* an alloy *comprising* tungsten and rhenium. The phrase *consisting essentially of* is a semi-closed limitation, whereas *comprising* is an open limitation. Therefore, it is unclear whether the body of the stent contains an alloy of consisting essentially of tungsten and rhenium, or if other metals that may have a material effect on the alloy may be included in the alloy because an open limitation (comprising) follows a semi-closed limitation (consisting essentially of). For examination purposes, Examiner has interpreted the claims to mean that the alloy consists essentially of tungsten and rhenium. This 112 rejection is the only new grounds of rejection herein.

Claims 1, 3, 6-8, and 32-35 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gianturco (4,800,882) in view of Mayer (5,630,840). Gianturco discloses a stent made from a wire that has a generally tubular shape (see figure 1). The stent can be made of many different metals, including tungsten (see column 3, lines

62-67). However, Gianturco does not disclose the stent is made of an alloy comprising tungsten and rhenium. Attention is drawn to Mayer, who teaches a wire stent of a tungsten based alloy having about 25 percent rhenium and the remainder (75%) tungsten (see column 11, lines 55-58) to provide a stent with sufficient flexibility (malleability) and radiopacity. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to make the stent of Gianturco of a tungsten based alloy including rhenium instead of just tungsten, as taught by Mayer, to provide a stent with sufficient flexibility (malleability) and radiopacity.

Claims 26-28 and 36-38 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gianturco (4,800,882) in view of Mayer (5,630,840) and Campbell (5,632,840). The combination of Gianturco and Mayer does not disclose a drug-polymer coating on the stent. Attention is drawn to Campbell, who teaches the use of a drug-polymer coating on stents to allow the stent to deliver drugs to a treatment site. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to include a drug-polymer coating on the stent of the combination of Gianturco and Mayer, in the manner taught by Campbell, to allow the stent to deliver drugs to a treatment site.

(10) Response to Argument

Appellant argues the rejection set forth in the combination of Gianturco and Mayer ignores the structural differences between the two, particularly that Mayer requires a jacket surrounding the alloy core. However, Examiner points out that at no

point was the structure of Mayer (particularly the jacket) relied upon in the rejection.

Mayer is used to show a tungsten-rhenium alloy is a known material used in the stent art.

Further, Examiner notes that appellant has provided no *evidence* to show that the alloy material of Mayer could not function as a stent without the jacket. The jacket is used to provide resilience to the Mayer stent. However, in situations where resilience is not required or desired (as in Gianturco), one of ordinary skill in the art would recognize that the inclusion of a resilient jacket would be undesirable. By creating a stent of an alloy of tungsten and rhenium, the physical properties of a stent desired by Gianturco would not be lost. This is supported in Mayer at column 6, lines 13-14, with Mayer stating that the core material (which is made of the alloy of tungsten and rhenium) is ductile (malleable). This malleability is another material feature desired by Gianturco (column 3, line 62 through column 4, line 4), and therefore provides further evidence that the use of the tungsten-rhenium alloy to make the stent of Gianturco would not destroy the functionality of the stent. The stent would still be plastically deformable, with the increased benefit of radiopacity (at column 5, lines 62-67 of Mayer) because of the rhenium material present in the alloy. Mayer further discloses at column 5, lines 11-13, with Mayer stating that inelastic prostheses, deformable by a balloon (meaning they are plastically deformable as Gianturco desires) are known in the art.

Examiner also takes the position that since the stent of Gianturco can be made from tungsten (see column 3, line 65), the mere addition of rhenium to the tungsten material to create an alloy would have been within the level of one of ordinary skill in the

art at the time the invention was made. This would create an added benefit over the stent of Gianturco in that the alloy creates a radiopacity in the stent to assist in real-time imaging of the device for more accurate deployment.

Further, it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice. *In re Leshin*, 125 USPQ 416. It is the Examiner's position that the alloy of tungsten and rhenium in the claimed concentrations is a known alloy in the stent art, as evidenced by Mayer. Therefore, Examiner takes the position that the use of a known material (the alloy of tungsten and rhenium as disclosed by Mayer) within a specific field (intravascular stents) to create a known device (the stent structure of Gianturco) is within the level of one of ordinary skill in the art.

(11) Related Proceeding(s) Appendix

No decision rendered by a court or the Board is identified by the examiner in the Related Appeals and Interferences section of this examiner's answer.

For the above reasons, it is believed that the rejections should be sustained.

This examiner's answer contains a new ground of rejection set forth in section **(9)** above. Accordingly, appellant must within **TWO MONTHS** from the date of this answer exercise one of the following two options to avoid *sua sponte* **dismissal of the appeal** as to the claims subject to the new ground of rejection:

(1) **Reopen prosecution.** Request that prosecution be reopened before the primary examiner by filing a reply under 37 CFR 1.111 with or without amendment, affidavit or other evidence. Any amendment, affidavit or other evidence must be relevant to the new grounds of rejection. A request that complies with 37 CFR 41.39(b)(1) will be entered and considered. Any request that prosecution be reopened will be treated as a request to withdraw the appeal.

(2) **Maintain appeal.** Request that the appeal be maintained by filing a reply brief as set forth in 37 CFR 41.41. Such a reply brief must address each new ground of rejection as set forth in 37 CFR 41.37(c)(1)(vii) and should be in compliance with the other requirements of 37 CFR 41.37(c). If a reply brief filed pursuant to 37 CFR 41.39(b)(2) is accompanied by any amendment, affidavit or other evidence, it shall be treated as a request that prosecution be reopened before the primary examiner under 37 CFR 41.39(b)(1).

Extensions of time under 37 CFR 1.136(a) are not applicable to the TWO MONTH time period set forth above. See 37 CFR 1.136(b) for extensions of time to reply for patent applications and 37 CFR 1.550(c) for extensions of time to reply for ex parte reexamination proceedings.

Respectfully submitted,

/Ryan J. Severson/

Examiner, Art Unit 3731

A Technology Center Director or designee must personally approve the new ground(s) of rejection set forth in section (9) above by signing below:

/DONALD HAJEC/

Director, Technology Center 3700

Conferees:

Anhtuan T. Nguyen

/Anhtuan T. Nguyen/

Supervisory Patent Examiner, Art Unit 3731

/Janet C. Baxter/
TC 3700 TQAS